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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,692	03/11/2004	Mark W. Becker	249.PIC2	6194

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GILEAD SCIENCES INC
333 LAKESIDE DR
FOSTER CITY, CA 94404

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/798,692	Applicant(s) BECKER ET AL.	
	Examiner Dr. Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-47 is/are pending in the application.
- 4a) Of the above claim(s) 34-36 and 38-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/26/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response filed 26 December 2006 to election requirement in Office Action mailed 25 July 2006 is acknowledged and entered.
2. The Art Unit Location for your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) has been changed to Art Unit 1657. To aid in correlating any papers for this application (i.e., 10/798,692), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.
3. Please note that upon arrival at the USPTO, each response/filing is sorted according to claims, remarks, amendment, transmittal etc. for scanning coding and incorporation in to the Electronic File Wrapper (i.e., IFW). In order to ensure that all the papers pertaining to a particular application are properly coded in the same application electronic file wrapper, and to further facilitate the prosecution; especially during a telephonic conversation/interview with applicant/applicants' representative, it is suggested that the following information be recited in the header of each page for any filing/response/amendment:
 - a. U.S. Non-Provisional Application Serial Number (e.g. 00/000,000);
 - b. Filing date for said application (e.g., 17 November 2002);
 - c. First Applicant's name (e.g., Smith Jones et al.);
 - d. Attorney Docket Number;
 - e. Group Art Unit Number (e.g., 1657);
 - f. Examiner's name (e.g., Dr. Kailash C. Srivastava);
 - g. Date of Office Action being responded to (e.g., 27 August 2006); and
 - h. Date of amendment/response (e.g., 27 April 2007)

Papers/responses filed according to above-stated guidelines immensely ameliorate the chances of papers lost during transaction/transmission, coding, indexing and placing the papers in IFW.

CLAIMS STATUS

4. Claims 1-33 remain cancelled.
5. Claims 38 and 41 remain amended.
6. Claims 34-47 are pending.

Restriction/Election

7. Applicants' election with traverse of Group I encompassing, Claims 34-40 and 42-47 and Claim 37 as the species for further prosecution filed 26 December 2006 to election requirement in Office Action mailed 25 July 2006 is acknowledged and entered. Applicants' traversal is on the ground (s) that no species election is required for Claims 42-47 because a concentration of "less than about 40% of diastereomer" is already recited in the elected Claim 37.

Applicants' arguments have been fully and carefully considered, are found persuasive. Note that limitations for Claims 42-47 is encompassed in the language "less than about 40% of diastereomer" recited in Claim 37. Therefore, the restriction requirement is still deemed proper and is made FINAL.

Accordingly, Claims 34-36 and 38-47 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP § 821.03.

8. Claim 37 is examined on merits.

Priority

9. Claim for domestic priority under 35 U.S.C. §119 (e) to U.S. Provisional application Serial Number 60/220,021 filed 21 July 2000 and under 35 U.S.C. §120 to each of Non-Provisional U.S. Applications 09/909,560 filed 20 July 2001, now abandoned and 10/354,207 filed 28 January 2003 also now abandoned is acknowledged.

Information Disclosure Statement

10. The Information Disclosure Statement (i.e., IDS) filed 26 December 2006 is acknowledged, has been made of record, considered and initialed form PTO 1449 is enclosed.

Objection To Specification

11. The specification is objected to because Line one of first page of specification, in its present form does not properly cite the application priority data. It is requested that the first line of the first page of the specification indicate that the instant application Claims priority to U.S. provisional and Non-provisional applications further indicating that both Non-Provisional U.S. Applications 09/909,560 filed 20 July 2001 and 10/354,207 filed 28 January 2003 have now been abandoned

Claim Rejections - 35 U.S.C. § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claim 37 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Recitation, “less than about 40%” renders Claim 37 incomprehensible, unclear and vague. The word “about” in and by itself means “in vicinity of” whereas the phrase “less than” gives the range along with the variation in the claimed number, or in vicinity of which claimed number or parameter should be present. Thus, this is a range in range situation, one range given according to the recitation, “about” and the other according to the phrase, “less than”. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the range and range situation is identified because of the recitation “less than” followed by the recitation “about” and then a number. The about giving the connotation of a range within the range.

Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

17. Claim 37 is rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Starrett et al. (EP 0481 214 A1).

Claim recites a compound having a particular structure, wherein said compound contains “less than about 40% of diastereomer”.

Starrett et al. teach a compound having the general structure (Page 3, Line 45 to Page 4, Line 2) having the same moiety (ies) as the compound structure in instantly claimed Claim 37. Thus, the reference discloses a compound which appears to be identical to the presently claimed compound. Since the structure disclosed in the prior art reference and that currently claimed in the instant invention appear to be same, the prior art compound inherently will have “less than 40% of diastereomer” (See e.g., *In re Best*, 195 USPQ 430, 433-CCPA 1977). Thus, the prior art explicitly and inherently teaches the claimed compound.

Therefore, the reference is deemed to anticipate the cited claims.

However, even if the reference compound and the claimed compound are not one and the same and there is, in fact, no anticipation, the reference compound would, nevertheless, have rendered the claimed compound obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that the reference discloses that members of the same genus and/or species as that claimed were known. Thus, the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.


Conclusion

18. For reasons aforementioned, no Claims are allowed.

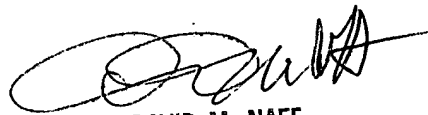
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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March 15, 2007


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 128/1657